RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1-8 and 16-17 were pending at the time of the Action. Claims 9-15 were withdrawn from consideration. Claims 1-8, 16, and 17 are presented for reconsideration.

B. Rejection Under 35 U.S.C. §112, second paragraph

Claims 1, 16, and 17 are rejected under 35 U.S.C. §112, second paragraph as being indefinite in reciting "...an effective amount of an auxin and an effective amount of a cytokinin" in that the metes and bounds of the claims are considered unclear. Applicants respectfully traverse, and note that a worker of ordinary skill in the art, upon reading the specification, would have reasonably been apprised of the metes and bounds of the claims. For instance, it would have been well known that various auxins or cytokinins have differing potency, and might be used at different absolute levels and ratios. Thus, concentrations of such hormones might be varied depending on media and growth conditions, as discussed in the Specification for instance at ¶0046, nevertheless producing the seedling as claimed. Further, Applicants submit that the production of a growing seedling is what defines the metes and bounds of the invention. Withdrawal of the rejection is therefore respectfully requested.

C. Rejection Under 35 U.S.C. §103(a)

Claims 1-8, 16 and 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,140,555 ("Reichert") in view of U.S. Patent 5,477,000 ("Saxena") and O'Connor-Sánchez (*Pl. Cell Rep*. 21:302-312, 2002). Applicants respectfully traverse as follows:

1. Combining the cited references changes their principle of operation

The Action combines Reichert, O'Connor-Sánchez and Saxena to arrive at the present rejection. However, Applicants respectfully submit that such a combination changes the

principle of operation of these references, in particular the principle of operation of the primary reference, Reichert. For instance, regarding claim 1, steps (a-c), as well as claims 16-17, the Action, at pages 4, 6, and 7, asserts that O'Connor-Sánchez teaches germinating corn seed on media containing auxin and cytokinin, while Reichert teaches isolating a nodal section and culturing the nodal section on "induction" media. Applicants note that Reichert, at column 3, lines 62-63, is discussing methods "to initiate **organogenic callus cultures**" [emphasis added; see Reichert, col. 3, l. 64-65], and uses media containing 2 auxins (2,4-D and picloram), but **no cytokinin**. Additionally, at col. 10, l. 65, to col. 11, l. 15, Reichert is explicitly discussing use of **shoot induction media** for organogenesis, **not callus-induction media** for callus formation (whether organogenic or otherwise).

Likewise, Saxena describes "direct differentiation" or "direct shoot morphogenesis" [*e.g.* col. 5, l. 4-10], *i.e.* an organogenic approach for obtaining regenerated plants. For instance, in Example 2 bridging cols. 9-10, Saxena describes culture conditions as pea seeds germinate, and explicitly notes that no callus formation occurs, while the "direct differentiation of regenerants" described in additional examples in col. 11, including Table 4, also indicates that other plants were produced **without a callus growth step**.

In contrast to Reichert, O'Connor-Sánchez is stated to teach use of media containing both auxin and cytokinin, to obtain, at least initially, morphogenetic organogenic **callus**. Thus, Reichert and O'Connor-Sánchez utilize distinct growth conditions to obtain developmentally distinct tissues, one being multiple shoots obtained via organogenesis on **shoot induction media** (Reichert), the other being "morphogenetic" organogenic callus from growth on **callus induction media** (O'Connor-Sánchez). Combining Saxena, which explicitly teaches that explant isolation is unnecessary ("...Contrary to popular belief, the isolation of explant is not necessary to induce

shoot regeneration." [column 12, lines 37-39]), with Reichert would also change the principle of operation of Reichert.

> "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)...The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.). [M.P.E.P. 2143.01 VI]

In view of the above, Applicants respectfully submit that no reasoned *prima facie* basis for obviousness has been provided in the Action, and withdrawal of the rejection is respectfully requested.

2. The references, as combined, provide no expectation of success

The O'Connor-Sánchez and Reichert references utilize media comprising distinct types of plant growth regulators. Thus, Reichert, as asserted in the Action, uses media without cytokinin. In contrast, Applicants note that, at least for the maize genotypes being studied by O'Connor-Sánchez, even the presence of auxin and cytokinin (*e.g.* their medium ZHM) did not necessarily lead to organogenic callus cultures (*See* Table 1, and discussion starting at p. 305, left column, 1st paragraph of "Results"). Rather, according to O'Connor-Sánchez, only use of "MPC" medium, and additionally containing adenine, routinely led to organogenic cultures with "multiple shoot meristems." Further, according to O'Connor-Sánchez, culture in the dark was necessary for organogenic/embryogenic-like callus to develop (*e.g.* p. 303, right column), while culture in light led to organogenic callus. Culture in the dark was not done by Reichert, and Reichert's culture in light led to organogenic callus, which is distinct from the embryogenic callus recited in the present claims.

Saxena is asserted in the Action as relating to use of various plant growth regulators including cytokinins and auxins. However the Action's reasoning that "...any auxin and any cytokinin or a combination thereof could be used as growth regulators..." is cursory and unsupported with respect to the present claims, in that Saxena provides no teaching or suggestion that an embryogenic approach, as presently described, would be beneficial, or that embryogenic callus would even be produced by applying the teachings of Saxena as a whole. For instance, Saxena focuses on achieving multiple regenerated plants via one or more growth phases where at least one shoot is formed and differentiates, or "direct shoot morphogenesis" occurs (*e.g.* see col. 4, l. 3-5, or col. 12, l. 42-43 of Saxena), instead of proceeding via an embryogenic callus-based tissue culture approach as presently required.

Such picking and choosing of disparate elements from these references, in addition to being tainted by hindsight reasoning, would have led to **no reasonable expectation of success** in practicing the invention as currently claimed, in particular to obtain embryogenic callus as presently recited. M.P.E.P. 2143.02. While the Action states at page 10 that there would have been a reasonable expectation of success, Applicants submit that this assertion is cursory and unsupported with respect to the presently claimed invention which is directed toward utilizing formation of **embryogenic callus** (*e.g.* see Example 3- "Direct induction of embryogenic culture")) without an intervening organogenic callus as is contemplated by O'Connor-Sánchez. Applicants note that "embryogenic callus" is known in the art as being callus which can regenerate a plant through somatic embryogenesis: "...the formation of somatic embryos which have both shoot and root initials and are capable of developing into whole plants..." (*e.g.* see Saxena at col. 1, l. 67, to col. 2, l. 2). In contrast, "organogenic callus" is known as callus which can regenerate "...an organ, a shoot which later develops roots to produce a complete plant..." (*e.g.* see Saxena at col. 1, l. 65-66).

. On the contrary, a skilled worker would have understood that, if anything, organogenesis would occur if teachings of O'Connor-Sánchez and Saxena were combined with Reichert. Saxena also **teaches away** from the present invention by focusing on use of intact seed and an organogenic, non callus-based approach. O'Connor-Sánchez describes approaches requiring formation of organogenic callus. In sum, all elements required to establish a *prima facie* case of obviousness of claim 1 are lacking. As such, the rejection is believed mistaken, and withdrawal of the rejection is thus respectfully requested.

3. All claims limitations must be considered

Regarding claims 16-17, for instance at pages 5-7, the Action repeatedly asserts that surface sterilization of a seed could be interpreted as "priming" a seed. Applicants respectfully submit that this represents a misunderstanding of a term well known in the art, and that the reference is not apt since "surface sterilization" is distinct from "seed priming." For instance, "priming" a seed is well known to represent a change in the physiological state of a seed with respect to its ability to germinate, which is not the object or result of surface sterilization. Likewise, priming does not require that sterilization occur, while sterilization does not require that priming is occurring. The components of a solution for surface sterilization would also be distinct from the components of a solution being used for seed priming. Further, the length of time typically required for priming to occur (*e.g.* multiple hours or days of soaking (imbibition) of seed in an appropriate solution) would be understood to be deleterious for seed viability if a seed were to be soaked for such an extended period of time for instance in bleach or ethanol, as is often done for surface sterilization, *e.g.* a seed treated with bleach in such a manner would clearly be expected to lose viability. Rather, the sterilant being utilized is a biocide, and is biocidal not just to contaminating microorganisms, but also would be to the cells of a seed meristem, and is being utilized specifically so that it is only briefly present on the outer surface

of a seed, not penetrating the seed coat to reach meristematic cells. In contrast, priming requires imbibition and contact of a solution with the interior of a seed. As such, the **"seed sterilization" of Saxena as asserted in the Action is not at all equivalent to "seed priming"** as recited in claims 16-17. The other asserted references do not cure this defect in the reasoning of the Action with respect to claims 16-17.

Applicants also submit that claim 1, step (c), as well as claim 16, step (d) and claim 17, step (d), explicitly recite use of "callus induction media." However, the Action at pages 4, 6, and 7, apparently confuses "shoot induction medium" with "callus induction media" in asserting that Reichert column 10, line 65, to column 11, line 15, renders these claims obvious. Such media are distinct, for instance in view of the amount and ratio of plant growth regulators that would be required to yield the developmentally distinct outcomes of callus on the one hand, or shoots on the other hand. Thus, the limitation "callus induction media" has not been properly considered, since the reference is not relevant to this claim limitation and the reasoning is not apt.

Therefore, because the claim limitations "priming a...seed" and "callus induction media" have not been properly considered, withdrawal of the rejections is respectfully requested.

D. Conclusion

In view of the foregoing, Applicants submit that the claims are allowable and respectfully request that the application be passed to issue.

The Examiner is invited to contact the undersigned attorney at (214) 259-0931 with any questions, comments or suggestions that may expedite the prosecution of the above-referenced patent application.

Respectfully submitted,

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